User Manual

MEGAPULSE SENIOR 265
Model 92

CE
0120

General Information

This manual provides the necessary information for the installation and operation of the Megapulse Senior 265.

These instructions must be studied before putting the unit into operation.

The information contained in this manual is subject to change without notice.

No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of EMS Physio Ltd.

The Megapulse 265 is a continuous and pulsed shortwave therapy unit.

Shortwave therapy can be applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, resolution of haematomas and for pain relief.

It is intended that the Megapulse Senior 265 is only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Record of Amendments

ISSUE	COMMENTS	DATE
2	Initial Issue	08/12/2006
3	Revised	01/10/2007
4	Revised	17/11/2008
5	Troubleshooting guide and EMC tables added	22/03/2010
6	Revised	28/09/2010
7	Note about use of Flexipulse electrode added.	20/07/2011
8	Declaration of conformity amended	06/10/2011
9	Revised for protocols	17/01/2014
10	Declaration of conformity revised	26/06/2014
11	Updated for new GUI	27/12/2014

EC Declaration of Conformity

Product Name	Megapulse Senior 265
Model Number	(92) EMS265

EMS Physio Ltd
Grove Technology Park, Downsview Road
Wantage, Oxfordshire, OX12 9FE, United Kingdom

Declares that the device listed above is in conformity with the essential requirements and provisions of the following EC Council Directives:

Directive	Conformity assessment route
2011/65/EU	Annex II, module A (768/2008/EC) (RoHS)
93/42/EEC	Annex II of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd. Class IIb according to Annex IX of 93/42/EEC

Signature M Bowles

Position	Operations Director
Date	2 February 2015
Date first issued	8 December 2006

Contents

	page
Title	1
General Information	3
Record of Amendments	3
Declaration of Conformity to 93/42/EEC	4
Contents	5
Warranty	6
Introduction	7
Precautions & Contraindications	10
Technical Specification	12
Accessories and Environmental	14
Controls and Markings	15
Installation	19
Operating Instructions	20
Maintenance	33
Troubleshooting	34
EMC Tables	35
Essential performance	39

Warranty

This EMS Physio Ltd., (hereinafter called the company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product:-

only if assembly operations, re-adjustments, modifications or repairs are carried out by persons authorised by it,

only if the product is used in accordance with the instructions for use,

only if the electrical installation of the relevant room complies with the appropriate national requirements.

Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, electrodes, electrode covers and batteries, are excluded from the above warranty.

Introduction

Shortwave Therapy
Shortwave refers to electromagnetic radiation in the frequency range 2 to 100 MHz. Shortwave therapy is the application of electromagnetic energy to the body at shortwave frequencies. At these frequencies the electromagnetic energy is converted to thermal energy by the induction of circulating currents in the tissue and dielectric absorbtion in insulating tissue. Shortwave therapy units may produce output power levels of up to 500W providing significant heating to the area of the body being treated. For this reason the treatment is often called shortwave diathermy (through heating). To avoid equipment such as shortwave therapy units interfering with radio communications, certain frequency ranges are designated by international agreement as ISM (Industrial, Scientific and Medical) bands. These are shown in the following table:-

Centre Frequency MHz	Frequency Range MHz	Maximum Radiation Limit
6.78	6.765-6.795	Under Consideration
13.560	13.553-13.567	Unrestricted
27.120	26.957-27.283	Unrestricted
40.680	40.66-40.70	Unrestricted
433.92	433.05-434.79	Under Consideration
915	902-928	Unrestricted
2450	2400-2500	Unrestricted
5800	5725-5875	Unrestricted
24125	24000-24250	Unrestricted
61250	61000-61500	Under Consideration
122500	122000-123000	Under Consideration
245000	244000-246000	Under Consideration

Shortwave therapy equipment normally uses the band centred on 27.12 MHz. This corresponds to a wavelength, in a vacuum, of approximately 11 metres.
Shortwave therapy is normally applied at a level which produces detectable heating and the benefits are those associated with the heating effect - encouragement of healing, pain relief, reduction of muscle spasm, increase in mobility etc.

The difference between shortwave therapy and other methods of

heating is that it provides “deep heat”. Other heating techniques such as infrared therapy, hot-packs etc., provide the heat externally whereas shortwave therapy generates heat within the tissue.
As with any electrotherapy, there are several potential dangers associated with shortwave therapy. Since relatively high powers are used, there is the possibility of producing burns if the patient is unaware of the heat due to reduced thermal sensation, or if the patient does not know what to expect during treatment. Metal in treatment area will provide low impedance paths to the induced radio frequency current, producing local heating and the possibility of burning. In particular, treatment should never be given in the area of metal implants, metal jewellery, buckles etc must be removed and treatment must never be given with the patient on metal framed couches or chairs. Patients with implanted electronic devices such as cardiac pacemakers must not be treated. Other equipment, including patient connected devices, may be adversely affected when in close proximity to shortwave therapy equipment.

Pulsed Shortwave Therapy
Conventional shortwave therapy equipment described above, produces a continuous wave output at 27.12 MHz. Pulsed shortwave therapy equipment delivers the energy in pulses or bursts of shortwave energy. The pulses are typically 20 to 400 microseconds in duration (pulse width) and are repeated with a frequency of 5 to 800 Hz (pulse frequency). As with other modalities such as ultrasound, it is found that delivering the energy in pulses is often therapeutically more beneficial that providing the same amount of energy in continuous wave form. Pulsed shortwave therapy appears to be effective for many conditions especially in the early stages of recovery.

Because the output is pulsed, the average output power levels can be very low (less than 1W) and still produce effective treatment.

The Megapulse Senior 265 in pulsed mode and with a Monopulse applicator provides a peak power of up to 200W and average powers from a few mW to 64W.

As the power levels are lower than with conventional shortwave therapy equipment, some of the potential dangers associated with the modality no longer apply. At average powers of less than 5 W, treatment may be given over areas containing metal implants, through wound dressings or plasters, and on couches or chairs with metal frames. A list of necessary precautions and contraindications is provided in the following sections.

Precautions & Contraindications

Precautions

The function of certain implanted electrical devices, for example pacemakers, may be adversely affected during treatment with shortwave therapy. In case of doubt, the advice of the physician in charge of the patient should be sought.

The function of other patient connected equipment may be adversely affected by the operation of shortwave therapy equipment.

Hearing aids should be removed.

Treatment should not be given through clothing although it is permissible to treat through a dressing or plaster in pulsed modes.

In pulsed modes areas containing internal metallic implants may be treated at low power levels (less than 5 W average power) without special precautions.

At average power levels above 5 W the following additional precautions apply:

External conductive material should be removed from the immediate treatment area.

Patients should not be allowed to come into contact with conductive parts which are earthed or which have an appreciable capacitance to earth and which may provide unwanted pathways for the radio-frequency current. In particular, beds or chairs with metal frames should not be used.

The connecting cables associated with electrodes should be positioned in such away that contact with the patient or conductive or energy absorbing objects is avoided. The Megapulse Senior 265 has cable retaining clips on both electrode arms.

The electrode cables should be positioned so that they do not come into contact with the body work or top panel of the equipment during use.

The electrode cables and plugs may get hot when used at high output levels for prolonged periods. Allow to cool after treatment before disconnecting.

Contraindications

Tumours, due to the risk of increased growth or metastatic activity.

Pregnancy, do not treat the lower abdomen, back or pelvis.

Menstruation, do not treat lower back or abdomen due to risk of increased bleeding or pain.

Cardiac conditions, do not treat the chest area or near the cervical ganglion.

Cardiac pacemakers, especially demand type, or any other implanted electronic device.

Patients with reduced thermal sensitivity in the proposed treatment area should not be treated with shortwave therapy.

Technical Specification

General	
Power Input	100-240 Vac 50/60 Hz
Classification (EN60601-1)	Class 1, Type BF
Mains Fuses	2 x T10A (5 x 20 mm)
Size (height x width x depth)	940 x 470 x 470 mm
Weight	38 kg (excluding electrodes)
Treatment Programs	10 user-defined set-ups

Shortwave	
Frequency	27.12 MHz
Maximum Output Power	400 W in continuous mode 1000 W peak in pulsed modes
Modes	Continuous, 3 in 3, 2 in 3 and 1 in 3
Pulse Frequency	5 - 800 Hz
Pulse Width	20 - 400 µs
Tuning	Automatic
Treatment Timer	0 to 30 minutes

The Megapulse Senior 265 is designed to operate from any 50/60 Hz single phase supply between 100 and 240 Vac capable of supplying 1 kVA. Connection is via an IEC socket at the rear of the unit.

All information on model, serial number, and month/year of manufacture is located on the rear panel.

Each Megapulse Senior 265 is supplied with a detachable mains cable, spare fuses, a pair of 100mm capacitive electrodes, output tester and this manual.

The Megapulse Senior 265 has been designed to meet the requirements of BS EN 60601-1:1990 (BS5724: Part 1:1989) "Medical Electrical Equipment, Part 1: General requirements for Safety", BS EN 60601-2-3:1991 “Medical Electrical Equipment, Part 2.3 Particular requirements for the safety of shortwave therapy equipment".

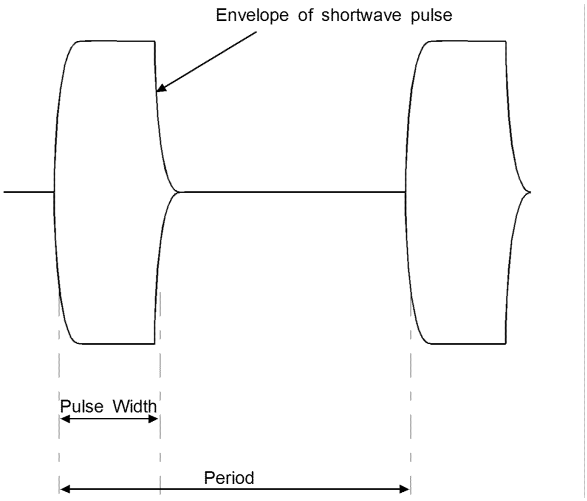

Fig.1 Pulsed Output Waveform

The pulse width may be set to 20, 40, 65, 100, 200 or 400 µs.
The Period may be from 1.25 ms (800Hz) to 200 ms (5Hz)

The duty cycle (%) is given by:

Pulse Frequency (Hz) x Pulse Width (µs) / 10000

In 3 in 3 mode the output pulse train is continuous

In 2 in 3 mode the pulses are on for 2/3 second and off for 1/3 second during each second of treatment.

In 1 in 3 mode the pulses are on for 1/3 second and off for 2/3 second during each second of treatment.

Environmental Conditions for Transport and Storage

Temperature	-10 to +35 C
Relative Humidity	5 to 95%
Atmospheric Pressure	500 to 1060 hPa

Accessories

For continued safety, only electrodes and cables supplied by EMS Physio Ltd. should be used with the Megapulse Senior 265.

Catalogue Number	Description
SLA990	Monopulse applicator
SLA991	Flexipulse applicator
SLA992	Pair of 100mm capacitive electrodes (standard issue)
SLA993	Pair of 50mm capacitive electrodes
SLA996	Pair rubber electrodes,180x120mm, with felt spacers
SLA9960	4 felt spacers for SLA996
SLA997	Pair rubber electrodes,260x180mm, with felt spacers
SLA9970	4 felt spacers for SLA997

Supplied with each unit is a detachable mains lead suitable for the country to which it is delivered. Replacement or additional mains leads are shown below.

EMS Part Number	Description
6-85	UK mains lead
6-112	European mains lead
6-119	North America mains lead

For other countries contact EMS Physio Ltd. or the agent from whom the unit was purchased.

Environmental

At the end its life, the Megapulse Senior 265 should not be disposed of as unsorted general waste.

Advice on appropriate disposal is available from EMS Physio Ltd.

Controls and Markings

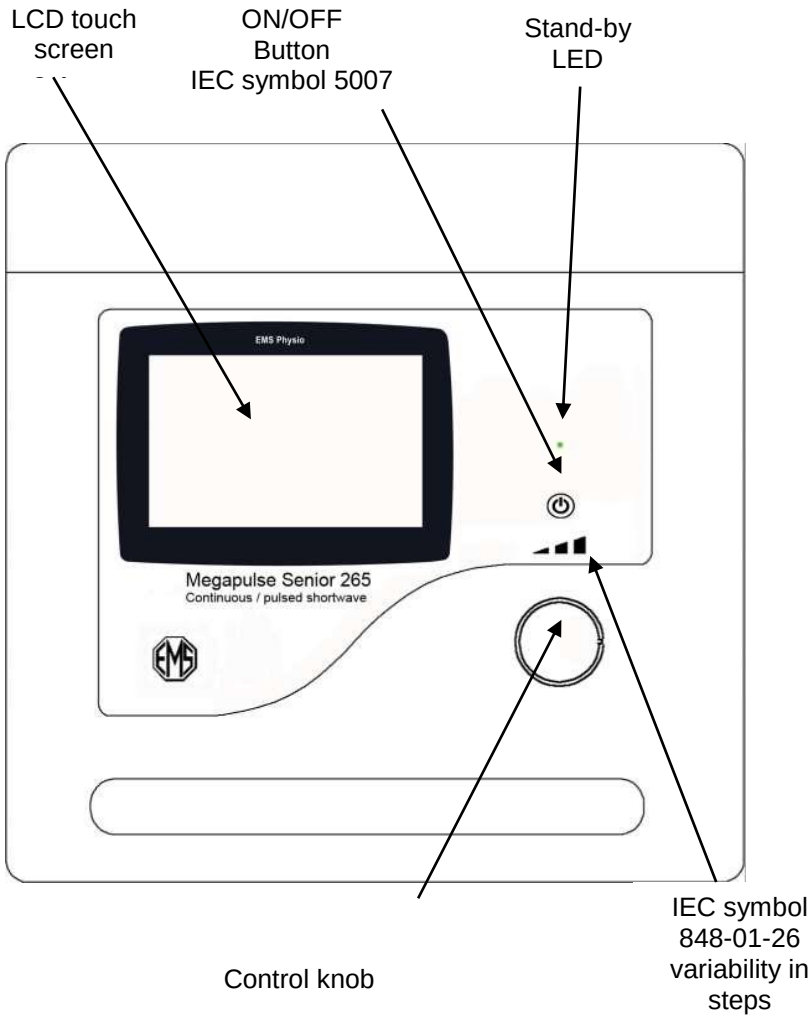

Fig. 3 Megapulse Senior 265 control panel

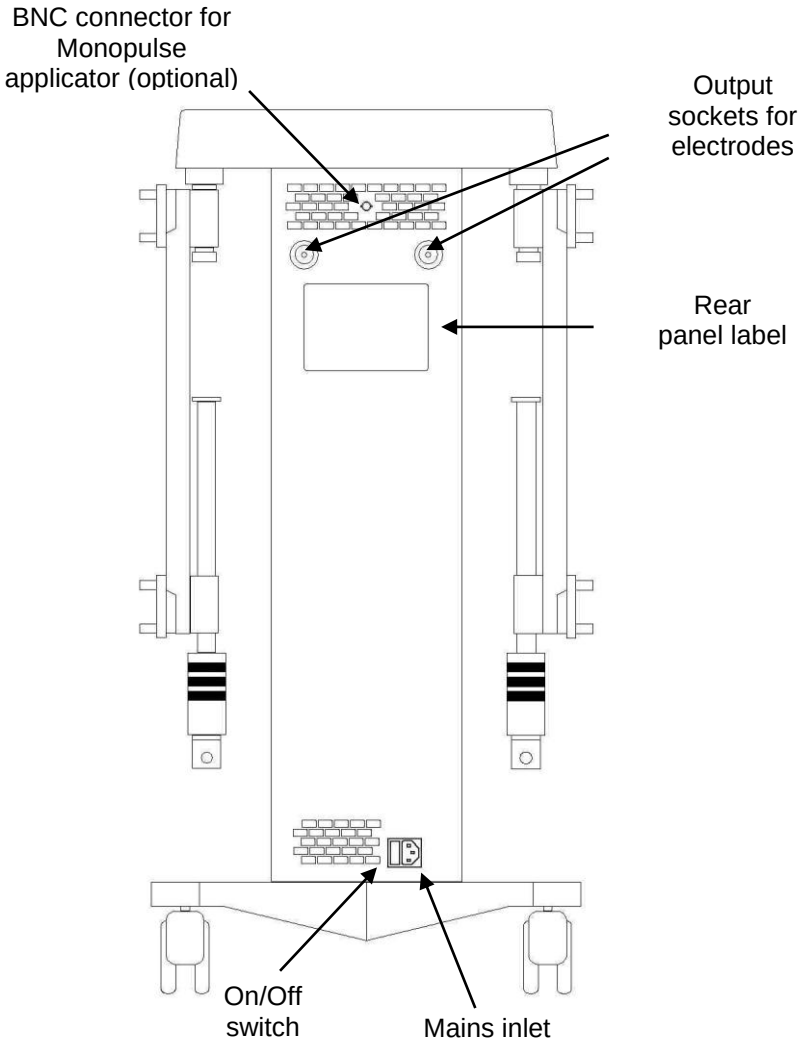

Fig. 3 Megapulse Senior 265 rear view

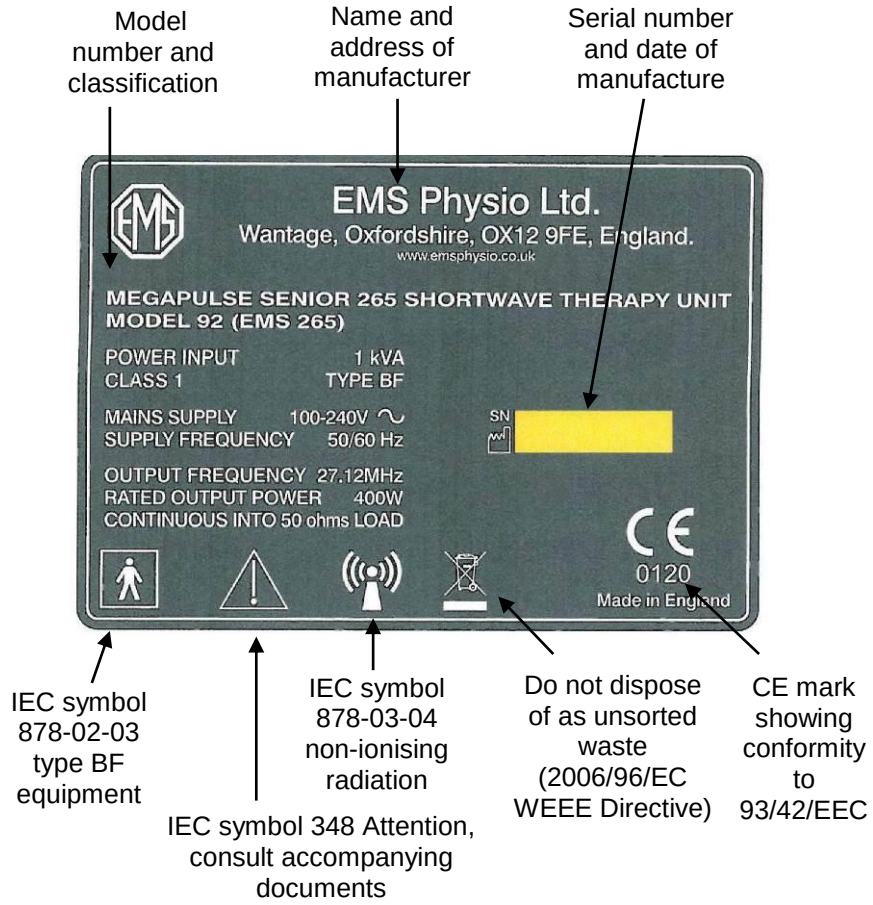
Model number and classification
Name and address of manufacturer
Serial number and date of manufacture
EMS Physio Ltd.
Wantage, Oxfordshire, OX12 9FE, England.
www.emsphysio.co.uk
MEGAPULSE SENIOR 265 SHORTWAVE THERAPY UNIT
MODEL 92 (EMS 265)
POWER INPUT 1 kVA
CLASS 1 TYPE BF
MAINS SUPPLY 100-240V
SUPPLY FREQUENCY 50/60 Hz
SN
OUTPUT FREQUENCY 27.12MHz
RATED OUTPUT POWER 400W
CONTINUOUS INTO 50 ohms LOAD
CE
0120
Made in England
IEC symbol 878-02-03 type BF equipment
IEC symbol 348 Attention, consult accompanying documents
IEC symbol 878-03-04 non-ionising radiation
Do not dispose of as unsorted waste (2006/96/EC WEEE Directive)
CE mark showing conformity to 93/42/EEC

Fig. 4 Rear Panel Label

The fuse label indicates the type and rating of the mains fuses

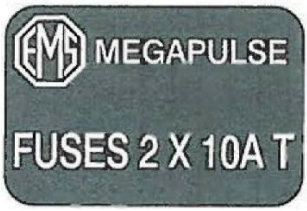

Fig. 5 Fuse Label

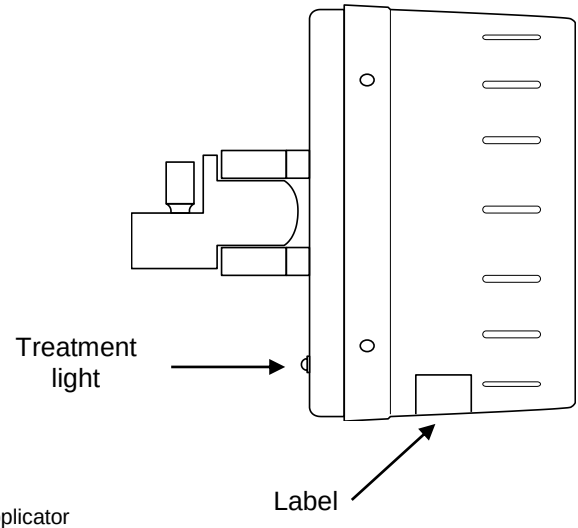

Fig. 6 Monopulse Applicator

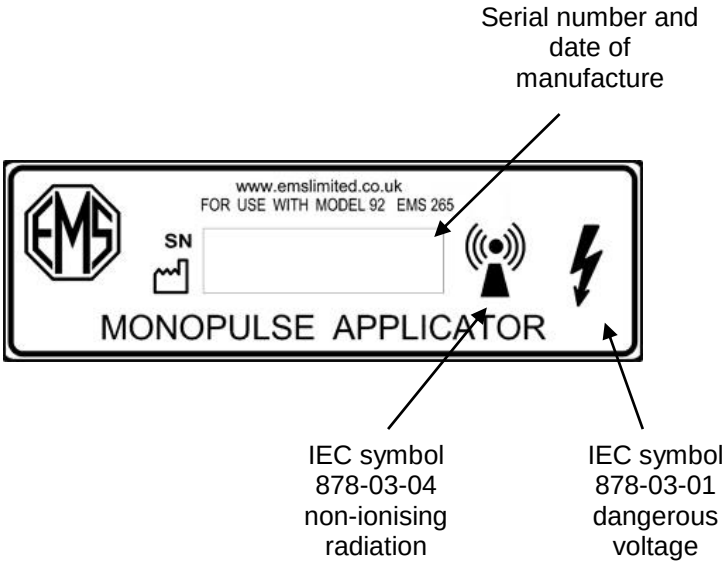

Fig. 7 Monopulse Label

Installation

Upon receipt, check for any visible damage which may have occurred in transit. If any signs of damage are found then retain all packing material and inform the carrier and the Company or its agent from whom the unit was purchased.

If not already fitted, connect a suitable plug to the mains cable. The plug must have provision for an EARTH (GROUND) connection. The mains cable has the following colour code: BROWN is LIVE (LINE), BLUE is NEUTRAL and GREEN/YELLOW is EARTH.

The Megapulse Senior 265 unit must only be connected to a mains supply with a protective earth conductor. If the integrity of the earth connection is in doubt, do not connect the unit to the mains supply.

Operating Instructions

Power on sequence and general information

Connect the mains cable to the IEC socket on the rear of the unit and to a suitable power outlet. Switch on the unit using the mains switch adjacent to the IEC socket. The green standby indicator on the top panel will light. Pressing the ON button will cause the display to illuminate and show the EMS company logo and name, the model name and number, the firmware version and the serial number.

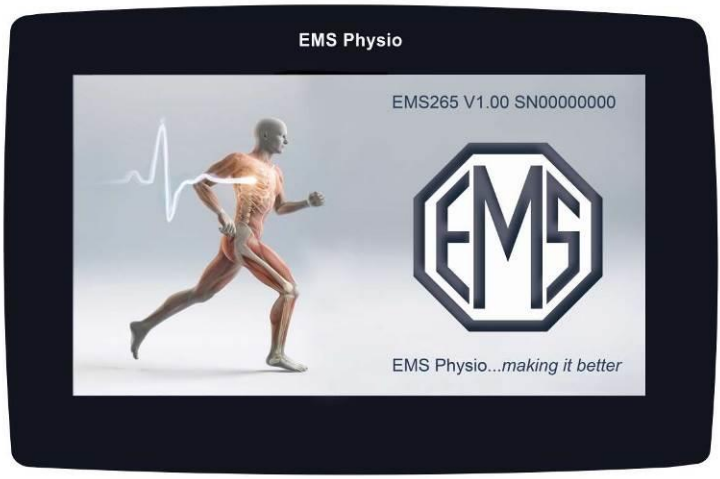

Fig.8 Start screen

After approximately 3 seconds, the unit will give a short beep and the display will show the home screen.

Standard key functions

Throughout the operation of the Megapulse Senior 265, all functions are accessed and controlled using the touch screen.

The rotary control is only used to initiate or end a treatment and increase or decrease the RF output.

During a treatment the touch buttons are all inactive.

The <Home icon> in the top left corner of most screens is used to exit from the current screen and return to the Home screen.

Home screen

This is the first navigational screen appearing at power-up, and has the following four options, which may be selected by touching.

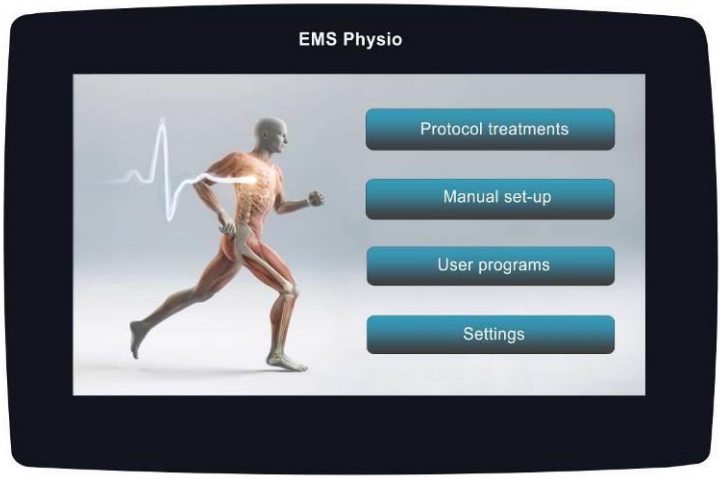

Fig. 9 Home screen

'Protocol treatments' brings up a list of clinical conditions, which can be stepped through using the up and down arrow buttons. Touching the anatomical figures will limit the displayed list to those relevant to the selected body area.

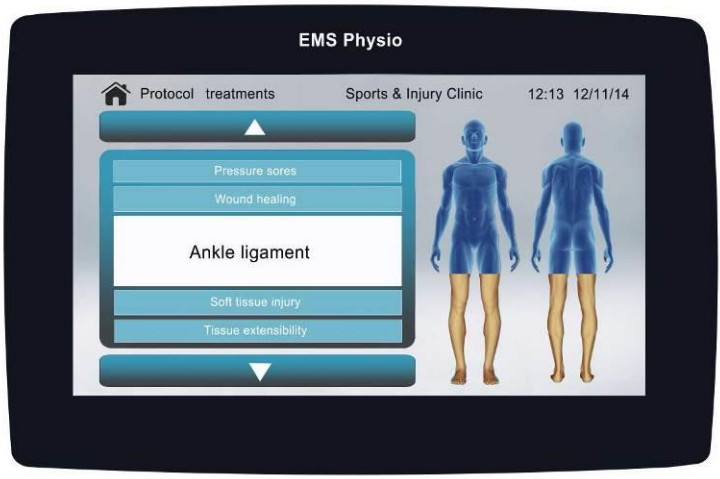

Fig. 10 Protocol treatments screen

Touching the highlighted condition will take you to a page with the parameters necessary to treat that condition already set. Most are 'greyed out' and can't be altered – only the electrode type can be changed to suit that being used, and treatment is initiated and power increased to the desired level by operating the rotary control.

When treatment is started, a rotating tuning icon will appear for a few seconds, then a flashing treatment icon will appear showing that the unit has tuned and power is being produced at the chosen level.

When in the selected treatment page, but not during an active treatment, touching the 'Protocol treatments' button will return you to the Protocols list.

Touching the 'Notes' button will take you to a QWERTY keypad that can be used to write any information pertinent to that treatment (or patient), which can then be stored using the 'Save' button.

Each treatment has its own separate notes file.

‘Manual set-up’

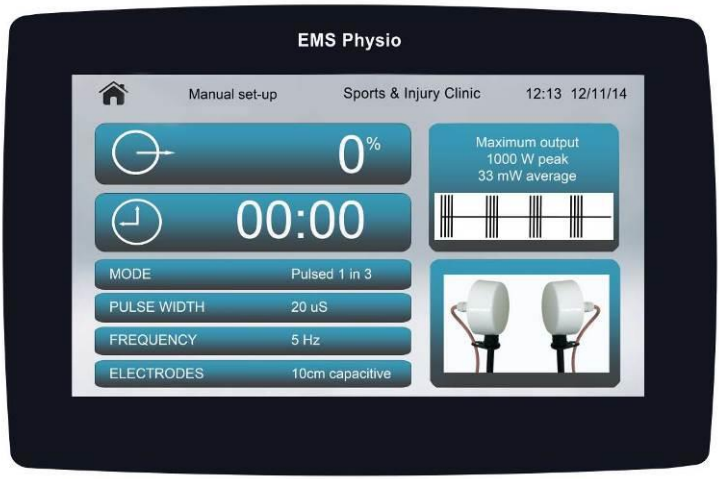

Fig. 11 Manual set-up screen

This screen allows the user to adjust every available parameter before initiating a treatment.

The treatment time can be set by touching the digits of the large time display, or by touching the clock icon which will take you to another screen where time may be entered numerically. Maximum treatment time is 30 minutes selected in 30 second steps.

The ‘MODE’ button has four settings which can be cycled through by touching. 1 in 3 gives 1/3 second on and 2/3 seconds off of pulsed output, 2 in 3 is 2/3 seconds on and 1/3 off, and 3 in 3 allows the pulsed output to flow uninterrupted.

‘Continuous’ means that the output is a continuous sine-wave with no pulsing at all (the ‘PULSE WIDTH’ and ‘FREQUENCY’ buttons will be greyed out when ‘Continuous’ is selected as they are no longer applicable).

If ‘MODE’ 1 in 3, 2 in 3 or 3 in 3 are selected, then ‘PULSE WIDTH’ gives you the option of 20, 40, 65, 100, 200 or 400us and ‘FREQUENCY’ gives you the choice of 5, 10. 20. 30, 50, 80, 100, 200, 400, 600 or 800Hz.

As the different settings are selected the maximum and average RF powers available for each will be calculated and displayed in the window at the top right of the display.

The ‘ELECTRODES’ button allows you to select which electrode is actually being used. A picture of the selected type will appear in the window at the bottom right of the display.

The Monopulse applicator is only suitable for pulsed treatments and is, therefore, not available for selection in continuous mode. All other electrodes may be used in continuous or pulsed mode. By selecting the electrode type with this option, the Megapulse Senior 265 limits the output power to a level that can safely be delivered with the electrode type chosen.

The maximum power display will change to reflect the limit for each electrode type.

Once the electrode(s) are positioned around the patient treatment is initiated by turning the rotary control up to the desired level (generally that which is most comfortable for the patient).

A rotating tuning icon will appear for a few seconds whilst the machine auto-tunes, then a flashing treatment icon will appear which indicates that power is being produced at the selected level.

Should the system fail to tune after 45 seconds a warning alarm will be heard and an error message will appear on the screen. Re-positioning the electrodes and/or ensuring no metallic objects such as chair or bed frames are nearby should allow tuning to occur.

‘User programs’ will select another screen displaying a list of programs. If nothing has been stored in any of them then the word ‘Empty’ will appear under the highlighted program. Pressing ‘Save’ will store whatever settings were last chosen via the ‘Manual set-up’ or ‘Protocol treatments’ pages. Different program slots to store onto can be selected by the UP/DOWN arrows. If you attempt to save onto a slot that isn’t empty, an ‘Are you sure?’ message will appear, allowing you to confirm or cancel the save operation.

Fig. 12 User programs screen

Saved settings are recalled by touching the highlighted program.

In a recalled program screen all parameters are still editable, and touching the ‘User programs’ button will return you to the user programs list screen. Note that any parameters changed will not be stored unless the user returns to the ‘User programs’ list and re-saves the settings.

A ‘Notes’ screen allows you to write and save information pertaining to each user program. The first line written here will appear as a title under the highlighted program number in the list page.

‘Settings’ brings up a page with options to navigate to sub-pages that allow adjustment of global system parameters and access to system information and help files.

Fig. 13 Settings screen

Changes made here will be remembered after powering down.

'Display' allows adjustment of the screen brightness.

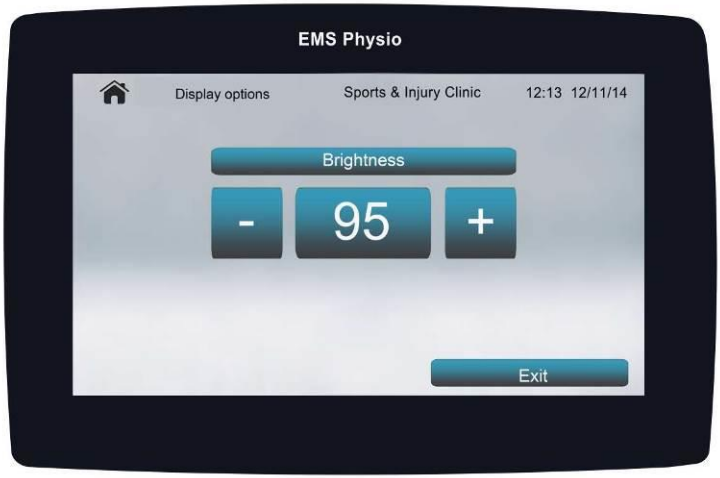

Fig. 14 Display options screen

'Sound' allows adjustment of sound settings such as the volume.

Fig. 15 Sound options screen

'Language' lets you choose any of the installed languages.

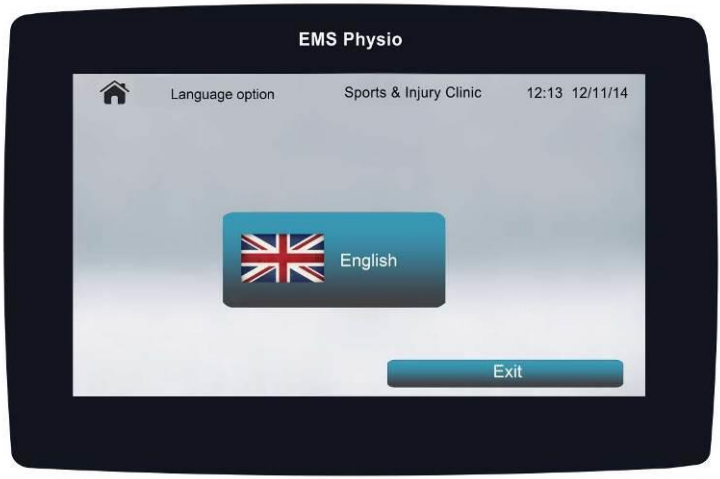

Fig. 16 Language options screen

'Clock' lets you set the time and date.

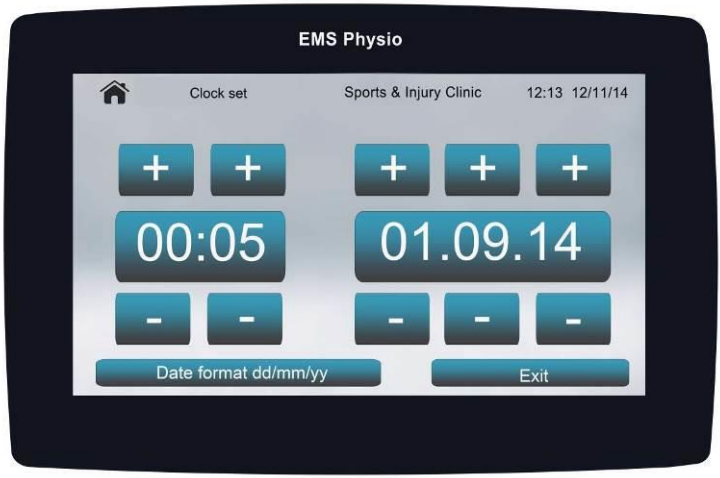

Fig. 17 Clock set screen

'Help' opens an on-screen user manual.

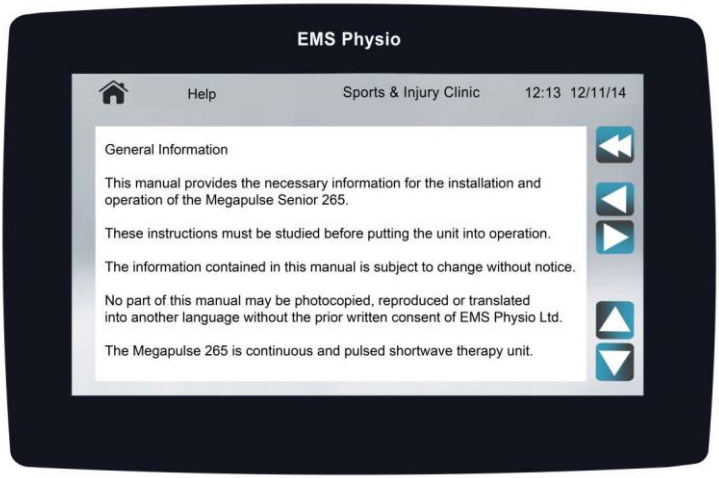
EMS Physio
Help
Sports & Injury Clinic
12:13 12/11/14
General Information
This manual provides the necessary information for the installation and operation of the Megapulse Senior 265.
These instructions must be studied before putting the unit into operation.
The information contained in this manual is subject to change without notice.
No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of EMS Physio Ltd.
The Megapulse 265 is continuous and pulsed shortwave therapy unit.

Fig. 18 Help screen

'Clinic' allows you to write in a name which will appear at the top of the screen.

'Maintenance' is intended for use by service engineers, and gives access to diagnostic information. It requires a pass code to access.

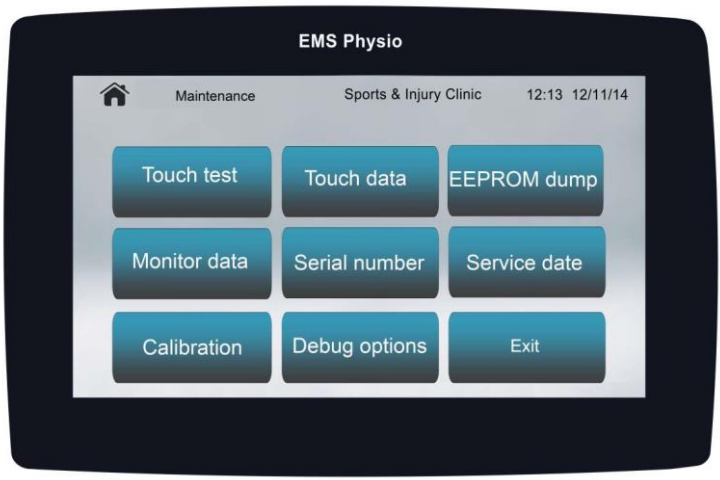

Fig. 19 Maintenance screen

'Monopulse Tuning' is greyed out and non-functional unless a Monopulse applicator is connected and selected. It opens a page with a bar graph that aids the adjustment and tuning of Monopulse applicators (by setting minimum reflected power).

Fig. 20 Tuning screen

'About' displays information about the unit such as its serial number, firmware versions and last date of calibration.

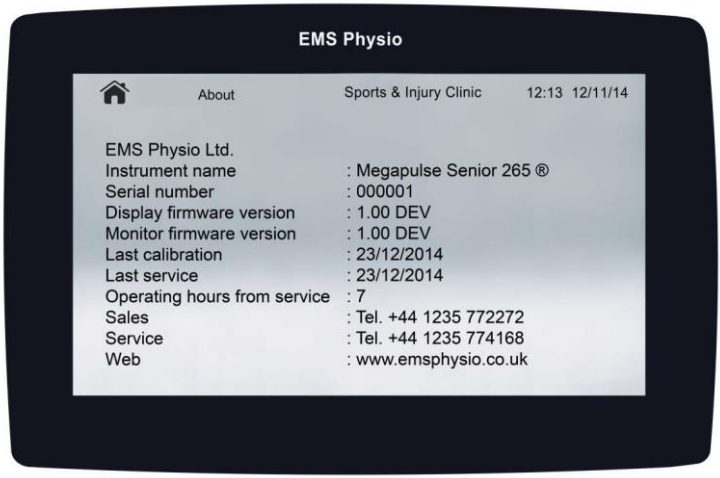
EMS Physio
About
Sports & Injury Clinic
12:13 12/11/14
EMS Physio Ltd.
Instrument name : Megapulse Senior 265 ®
Serial number : 000001
Display firmware version : 1.00 DEV
Monitor firmware version : 1.00 DEV
Last calibration : 23/12/2014
Last service : 23/12/2014
Operating hours from service : 7
Sales : Tel. +44 1235 772272
Service : Tel. +44 1235 774168
Web : www.emsphysio.co.uk

Fig. 21 About screen

Treatment using the Monopulse applicator

Attach the Monopulse applicator to one of the electrode arms and lock it into place by tightening the sleeve at the end of the arm Connect one end of the BNC cable supplied to the socket on the rear of the applicator and the other end to the BNC socket on the rear of the unit.

Slacken the arm handwheels and position the applicator over the treatment site so that the rim around the rim of the applicator is about 1 cm from the patient. Tighten the handwheels to prevent movement.

Make sure that Monopulse is selected for the electrode type.

To start treatment, turn the rotary control clockwise.
If the treatment time is zero, or the Monopulse applicator is not connected, the unit will give a short alarm to indicate that the output cannot be energised.

If the treatment time is not zero, the output of the Megapulse will be energised and the treatment time will begin to count down. The treatment icon will be displayed in the bottom right window of the screen and the treatment light on the rear of the Monopulse applicator will light. Advance the output control to the required level.

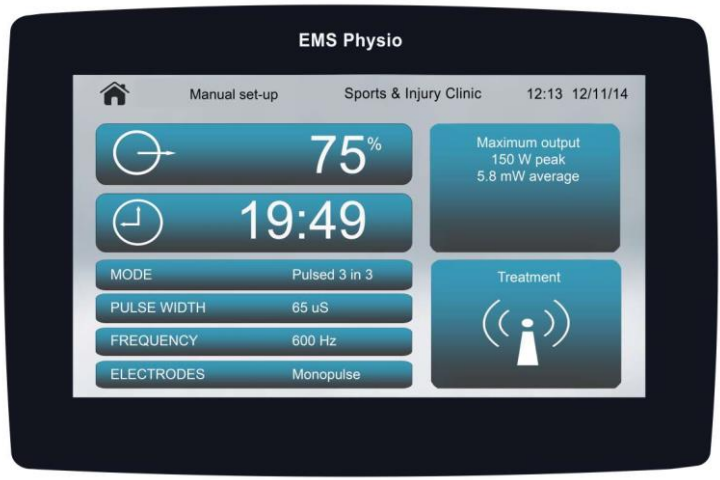

Fig. 22 Manual set-up screen

The output level is shown as a percentage of the maximum power available with the current set-up. In the example shown above, the output level is set to 75% of 200W peak and 7.8 average, giving an output of 150W peak and 5.85W average.

When the treatment time reaches zero, the pulsed shortwave energy from the monopulse applicator is terminated, the light at the rear of the applicator will turn off, the output display will show 0% and a three second alarm is sounded.

Treatment using rigid capacitive electrodes

Attach the 5 cm or 10 cm capacitive electrodes to the arms and secure in place by tightening the retaining sleeve. Connect the electrode plugs to the output sockets on the Megapulse Senior 265 rear panel. Ensure that the electrode cables are kept apart from each other using the cable retaining clips on the electrode arms.

Position the electrodes using the Megapulse arms so that the radio-frequency electric field from the electrodes will pass through the treatment site. Tighten the handwheels to prevent movement.

Make sure that the electrode type selected is the same as those being used. To start treatment, turn the rotary control clockwise.

If the treatment time is zero, the unit will give a short alarm to indicate that the output cannot be energised.

If the treatment time is not zero, the output of the Megapulse will be energised. Once tuned (if necessary) the treatment icon will flash in the bottom right window of the screen and the treatment time will begin to count down. Advance the output control to the required level - in continuous mode this is normally when the patient can feel warmth from the treatment. The presence of output from the electrodes may be verified using the fluorescent output tester which will light when placed near the electrodes.

The Megapulse Senior 265 has automatic tuning in order to optimise power transfer to the patient. While the unit is tuning, the treatment timer will not count down, and a rotating tuning icon will appear in the bottom right window of the display. Should the unit be unable to tune to the load provided by the electrodes after 45 seconds an alarm will sound and an error message appear. Turn off the output power using the rotary control, reposition the electrodes and try again.

When the treatment time reaches zero, the shortwave energy from the electrodes is terminated, the output display will show 0% and a three second alarm is sounded.

Treatment using flexible rubber capacitive electrodes

Connect the rubber electrode plugs to the output sockets on the Megapulse Senior 265 rear panel. Place the flexible electrodes in position using the felt spacers provided between the skin and the electrode. The electrode spacing is controlled by the number of felt spacers used.The operating procedure is the same as that for the rigid capacitive electrodes.

Maintenance

The Megapulse Senior 265 and monopulse applicator may be cleaned by wiping over with a damp cloth. The use of abrasive materials and cleaning solvents should be avoided.

Regularly (at least monthly) inspect electrode leads, cables and connectors for signs of damage.

The unit calibration should be checked at least annually.

After a total of 1000 hours of treatment time, a message will appear to remind the user that a service examination is recommended, and either EMS Physio or their distributor should be contacted. Pressing ‘OK’ will clear the message and allow the unit to be used, but it will reappear every time the unit is switched on until a qualified engineer resets the counter after a service.

The mains fuses are located at the rear of the unit in a compartment below the mains inlet. The compartment cannot be opened unless the mains lead is removed from the IEC socket. Information on fuse type and rating is given on the label adjacent to the mains inlet and in the Technical Specification section of this manual.

If the mains fuses continue to blow then EMS Physio qualified Service personnel must be called in.

There are no user serviceable parts inside the unit and it should not be opened.

Full servicing instructions are available on request.

Troubleshooting

Symptom	Action
Unit shows “Tuning” and “Treatment” will not begin.	Check correct electrodes have been selected. Check electrodes are securely connected. Check electrode cables are routed as described in relevant section. Ensure that metal framed beds, tables and chairs are not in the treatment area. Check electrodes are positioned directly opposite each other and either side of the treatment area.
Unit shows “Treatment” but no warmth can be felt by patient and flourescent indicator does not light.	Check correct electrodes have been selected. Check electrodes are securely connected. Check power output level is greater than 10%.
Unit shows “Over temperature”	Leave unit switched on and allow to cool for 15 minutes before switching unit off and then restarting unit.
	If the actions above do not resolve the problem please contact the manufacturer or an approved service agent for further advice.

Guidance and manufacturers declaration – Electromagnetic immunity.

The Megapulse Senior 265 is intended for use in the electromagnetic environment specified below. The customer or user of the Megapulse Senior 265 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic Environment Guidance
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Megapulse Senior 265, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=3.5\sqrt{P}/V_1$ $d=3.5\sqrt{P}/E_1$ 80MHz to 800MHz $d=7\sqrt{P}/E_1$ 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter according to the manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80MHz and 800MHz the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Megapulse Senior 265 is used exceeds the applicable RF compliance level above, the Megapulse Senior 265 should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as re-orienting or relocating the Megapulse Senior 265.

[b] Over the frequency range 10kHz to 80Mhz, field strengths should be less than 3 V/m.

1	**Guidance and manufacturers declaration – electromagnetic emissions**		
2	The Megapulse Senior 265 is intended for use in the electromagnetic environment specified below. The customer or the user of the 265 should assure that it is used in such an environment.		
3	**Emissions Test**	**Compliance**	**Electromagnetic environment - guidance**
5	RF emissions CISPR 11	Group 2	The Megapulse Senior 265 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
6	RF emissions CISPR 11	Class A	The265 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
7	Harmonic emissions IEC 6100-3-2	Class A	
8	Voltage fluctuations Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturers declaration – electromagnetic immunity			
The Megapulse Senior 265 is intended for use in the electromagnetic environment specified below. The customer or the user of the 265 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*T (>95% dip in *U*T) For 0,5 cycle 40% *U*T (60% dip in *U*T) For 5 cycles 70% *U*T (30% dip in *U*T) For 25 cycles <5% *U*T (>95% dip in *U*T) For 5 sec	<5% *U*T (>95% dip in *U*T) For 0,5 cycle 40% *U*T (60% dip in *U*T) For 5 cycles 70% *U*T (30% dip in *U*T) For 25 cycles <5% *U*T (>95% dip in *U*T) For 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 265 requires continued operation during power mains interruptions, it is recommended that the 265 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) Magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the Megapulse Senior 265

The Megapulse Senior 265 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the 265 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Megapulse Senior 265 as recommended below, according to the maximum output power of the communications equipment.

	150kHz to 80MHz $d=3.5\sqrt{P}/V_1$	**80MHz to 800MHz** $d=3.5\sqrt{P}/E_1$	**800MHz to 2.5GHz** $d=7\sqrt{P}/E_1$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80MHz and 800MHz the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Essential Performance

Power Input	100-240 Vac 50/60 Hz
Output Frequency	27.12 MHz (± 120 kHz)
Maximum Output Power (into 50 ohms)	400 W (± 30%) in continuous mode 1000 W peak (± 30%) in pulsed modes
Modes	Continuous, 3 in 3, 2in 3 and 1 in 3
Pulse Frequency	5,10, 20, 30, 50, 80, 100, 200, 400, 600, 800 Hz (± 10%)
Pulse Width	20, 40, 65, 100, 200, 400 µs (± 10%)
Treatment Timer	0 to 30 minutes

EMS Physio Ltd.
Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
UK

T: +44(0)1235772272
F: +44(0)1235763518
Email:sales@emsphysio.co.uk
Website: www.emsphysio.co.uk